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Pa 11303/00860

THE PATENTS ACT, 1970

REC'D 23 JUL 2003	
WIPO	PCT

IT IS HEREBY CERTIFIED THAT, the annex is a true copy of Application and provisional specification filed on 13.03.2002 in respect of Patent Application No. 247/MUM/2002 of Cadila Pharmaceuticals Ltd., Cadila Corporate Campus, Sarkhej-Dholka Road, Bhat, Ahmedabad, 382210, Gujarat, India, an Indian Company.

This certificate is issued under the powers vested in me under Section 147 (1) of the Patents Act, 1970. ....

.....  
Dated this 23<sup>rd</sup> day of June 2003

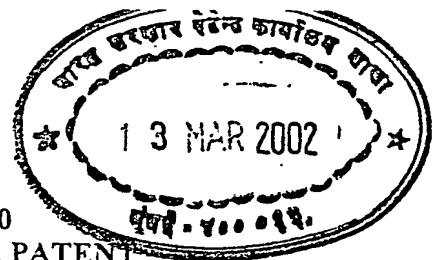
  
(N. K. GARG)

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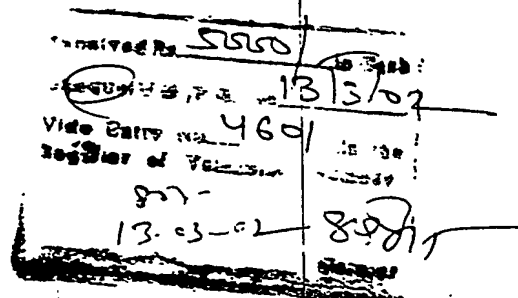


FORM 1  
THE PATENTS ACT, 1970  
APPLICATION FOR GRANT OF A PATENT  
(See section 5(52), 7, 54, AND 135 and Rule 33A)

1. We Cadila Pharmaceuticals Ltd., "Cadila Corporate Campus", Sarkhej-Dholka Road, Bhat, Ahmedabad, 382210, Gujarat, India, an Indian Company.
2. Hereby declare:-
  - a. That I am in possession of an invention for the Process for manufacturing pharmaceutical composition comprises of mycobacterium w in the treatment of Bronchial asthma attack
  - b. That the Provisional Specification relating to the invention is filed with this application.
  - c. That there is no lawful ground of objection to the grant of patent to me.
3. Further declare that the inventors for the said invention are
  - a. Dr. Rajiv I. Modi, Cadila Pharmaceuticals Ltd., "Cadila Corporate Campus", Sarkhej-Dholka Road, Bhat, Ahmedabad, 382210, Gujarat, India, Nationality, Indian.
  - b. Dr. Bakulesh Mafatlal Khamar, 201, "Ashdha", Vasundhara Colony, Gulbai Tekra, Ellisbrige, Ahmedabad - 380006, Gujarat, India, Nationality, Indian.
4. That we are the assignee of the true and first inventors
5. That our address for service in India is as follows: Dr. Bakulesh Mafatlal Khamar, 201, "Ashadha", Vasundhara Colony, Gulgai Tekra, Ellisbridge, Ahmedabad - 380006, Gujarat, India, Phone - 6560252, Facsimile no. 6430821.

Dr. Bakulesh M Khamar  
Date: March 9, 2002

247/mum/2002  
13/3/2002



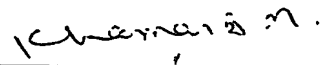
247 | मुंबई | 2002  
MUM

13 MAR 2002

ORIGINAL

6. That to the best of my knowledge, information and belief the fact and matters stated herein are correct and that there is no lawful ground of objection of the grant of patent to me in this application.
7. following are the attachment with this application:  
(a) Provisional specification (3 copies)  
(b) Statement and Undertaking on Form 3(3 copies)  
(c) Fees Rs. 5000/- (Rupees Five thousand only) in bank draft in bank draft in bank draft bearing no. 575455 dated 19/02/2002 on Corporation bank.
8. I request that a patent may be granted to me for the said invention.

Dated, this 9<sup>th</sup> day of March, 2002.

  
Dr. Bakulesh M Khamar  
FOR CADILA PHARMACEUTICALS LIMITED.

To,  
The Controller of Patents  
The Patents Office Branch  
Mumbai.



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**FORM 2**

**THE PATENTS ACT, 1970  
(39 OF 1970)  
THE PROVISIONAL SPECIFICATION  
(See section 10)**

1. PROCESS FOR MANUFACTURING PHARMACEUTICAL COMPOSITION COMPRISES OF MYCOBACTERIUM W IN THE TREATMENT OF BRONCHIAL ASTHAMA ATTACK
2. CADILA PHARMACEUTICALS LTD., "CADILA CORPORATE CAMPUS", SARKHEJ-DHOLKA ROAD, BHAT, AHMEDABAD, 382210, GUJARAT, INDIA, AN INDIAN COMPANY.
3. THE FOLLOWING SPECIFICATION DESCRIBES AND ASCERTAINS THE NATURE OF THIS INVENTION AND THE MANNER IN WHICH IT IS TO BE PERFORMED.

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**247** | युंवई | **2002**  
MUM

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ORIGINAL

**PROCESS FOR MANUFACTURING PHARMACEUTICAL COMPOSITION  
COMPRISES OF MYCOBACTERIUM W IN THE TREATMENT OF  
BRONCHIAL ASTHAMA ATTACK**

The invention relates to process for the preparation of formulations comprising a microorganism Mycobacterium w for the treatment of bronchial asthma.

Bronchial Asthma is defined as a disease characterised by an increased responsiveness of the trachea and bronchi to various stimuli and manifested by wide spread narrowing of the airways that changes in severity either spontaneously or as a result of treatment. It is characterised by:

- ☐ Episodic or chronic wheezing, dyspnea, cough, and felling or tightness in the chest.
- ☐ Prolonged expiration and diffuse wheezing on physical examination.
- ☐ Limitation of airflow on pulmonary function testing, or positive bronchoprovocation challenge test.
- ☐ Complete or partial reversibility of obstructive dysfunction after bronchodilator therapy.

The prevention of an attack comprises of eliminating 'trigger factors'. It includes measures to control house dust mite antigen, animal danders, avoidance of exposure to environmental factors including change place of work or residence, early treatment of upper respiratory tract and chest infections etc.

The management of an attack comprises of use of bronchodilators and Corticosteriods. They can be used orally, parenterally or in form of aerosols depending upon severity of disease and other factors. Corticosteriods and mast cell stabilizers like chromolyn sodium are also used to prevent the subsequent attack.

Administration of pharmaceutical composition made as per present invention is found to result in reduction in severity of disease and frequency of asthmatic attacks. The dependent on drugs is decreased and quality of life improves.

The present invention discloses such formulations and method of their manufacture and use.

Dated this 9<sup>th</sup> March 2002

*Bakulesh M Khamar*

Dr. Bakulesh M Khamar

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